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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/747,974  | 12/30/2003  | George M. Levinson   | 06335.00007         | 9013             |
| 22908   | 7590        | 08/30/2004           | EXAMINER            |                  |
| BANNER & WITCOFF, LTD.<br>TEN SOUTH WACKER DRIVE<br>SUITE 3000<br>CHICAGO, IL 60606 |             |                      | TSAL, CAROL S W     |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 2857                |                  |

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/747,974 | <b>Applicant(s)</b><br>LEVINSON ET AL. |  |
|                              | <b>Examiner</b><br>Carol S Tsai      | <b>Art Unit</b><br>2857                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/30/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 4-15, and 17-31 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Publication 2004/0039706 to Skowron et al.

With respect to claims 1, 2, 4, 5, and 22-24, Skowron et al. disclose a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements (see paragraphs 0003, 0017-0020, 0037, and 0039).

As to claims 9-11 and 27-29, A data management system having a universal hub, the universal hub interfacing with at least one add-on software module for specialized tracking of data unique for a particular manufacturing facility, the data selected from the group consisting of media growth promotion, sterility testing, media fills, bioburden, equipment maintenance and calibration, annual report, antibiotic assay, biological indicator, corrective and preventative

Art Unit: 2857

action, cleaning and disinfection validation and tracking, container closure integrity, endotoxin testing, filter integrity, package integrity, preservative effectiveness testing, and smoke studies, the system configured to collect and store the data, and generate a user report of the data, the user report providing document compliance with U.S. Food and Drug Administration requirements (see paragraphs 0003, 0017-0020, 0023, 0037, 0039, 0044, 0062, and 0063).

As to claims 14, 15, 17, and 18, Skowron et al. also disclose A data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure a first set of data, the system configured to collect and store the first set of data, and generate a first user report of the first set of data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the universal hub interfacing with at least one add-on software module for specialized tracking of a second set of data, the second set of data unique for a particular manufacturing facility, the second set of data selected from the group consisting of media growth promotion, sterility testing, media fills, bioburden, equipment maintenance and calibration, annual report, antibiotic assay, biological indicator, corrective and preventative action, cleaning and disinfection validation and tracking, container closure integrity, endotoxin testing, filter integrity, package integrity, preservative effectiveness testing, and smoke studies, the system configured to collect and store the second set of data, and generate a second user report of the second set of data, the first and second user reports providing document compliance with U.S. Food and Drug Administration requirements (see paragraphs 0003, 0017-0020, 0023, 0037, 0039, 0044, 0062, and 0063).

As to claims 6, 12, 19, 25, and 30, Skowron et al. also disclose the report is a configurable report having configurable records selected from the group consisting of data records to include, displayed fields, sort and grouping of data records, and formatting of data via a table, bar chart, pie chart, or other visual display (see Figs. 8-14 and 16-31).

As to claims 7, 13, 20, 26, and 31, Skowron et al. also disclose allowing a user to configure access of a specific individual with access to a predetermined specific to system function (see paragraph 0038).

As to claims 8 and 21, Skowron et al. also disclose the electronic communication between the hub and the equipment being accomplished by a link device that interfaces with the equipment used to measure the environmental data (see paragraph 0019).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skowron et al. in view of U. S. Publication 2004/0133453 to Jomini et al.

As noted above, with respect to claims 3 and 16, Skowron et al. disclose the claimed invention, except for the water quality detector being selected from the group consisting of detector, conductivity detector, total organic content detector, endotoxin detector, coliform detector, metal detector, and thermometer.

Art Unit: 2857

Jomini et al. teach the water quality detector being selected from the group consisting of detector, conductivity detector, total organic content detector, endotoxin detector, coliform detector, metal detector, and thermometer (see paragraph 0024).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Skowron et al.'s system to include the water quality detector being selected from the group consisting of detector, conductivity detector, total organic content detector, endotoxin detector, coliform detector, metal detector, and thermometer, as taught by Jomini et al., in order to measure an environment condition.

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Shah discloses a system for managing clinical trials including a Web client, a client, a server, and a patient records database.

Bognanno discloses a system and methods to perform automated validation and corresponding workflow Management.

Rash et al. disclose a system and method for maintaining environmental stabilization.

Alleckson et al. disclose an apparatus for reporting a patient's health parameter to a remote data management center. The apparatus has measurement units and a home hub.

***Contact Information***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carol S. W. Tsai whose telephone number is (571) 272-2224. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (571) 272-2216. The fax number for TC 2800 is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC 2800 receptionist whose telephone number is (571) 272-1585 or (571) 272-2800.

In order to reduce pendency and avoid potential delays, Group 2800 is encouraging FAXing of responses to Office actions directly into the Group at (703) 872-9306. This practice may be used for filing papers not requiring a fee. It may also be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify the examiner and art unit at the top of your cover sheet. Papers submitted via FAX into Group 2800 will be promptly forwarded to the examiner.



Carol S. W. Tsai  
Patent Examiner  
Art Unit 2857

08/23/04